REMARKS

Pending claims

Claim 1 has been amended to more clearly point out and distinctly claim the invention. Support for the newly introduced phrase "without fasting" can be found in the paragraph bridging page 18 and page 19. Also, Applicants have replaced the phrase "about 45 minutes" with the original phrase "less than 50 minutes", and the phrase "determine if the ratio of the second glucose concentration over the first glucose concentration is about 1.5 or larger, indicating that the patient is likely to be a diabetic" with the phrase "determine if the second glucose concentration is at least about 1.5 folds of the first glucose concentration, indicating that the patient is likely to be a diabetic." No new matter has been introduced. Six (6) Claims (claims 1–6) are pending.

Rejections Under 35 USC 112

Claims 1-6 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. For the following reasons, the Examiner's rejection is respectfully traversed.

Applicants submit that the invention is clearly described and taught in the specification. First, in the paragraph bridging page 18 and page 19, Applicants state:

> In an *in vitro* screening assay, subjects could come into an eye practitioner with or without fasting and have a tear sample taken using a first strip of the invention. The subject would then be given an oral carbohydrate load (e.g. 75 g of glucose) and a subsequent sample taken with a second strip of the invention after a defined time period (e.g. from 15 minutes to 30 minutes). The wicked portion of each of the first and second strips would be assayed for glucose, and, if there was a substantial rise in the tear glucose value during that time interval (e.g. 1.5 fold), then the person would be referred for follow-up and diagnosis to a general physician. No follow -up would be required if the person did not get this rise in tear glucose. [Emphasis added]

The example ("e.g., from 15 minutes to 30 minutes") of a defined period time illustrates the original limitation "less than 50 minutes." The experiments and their results (Figure 1) described in Example 1 further illustrate the original limitation "less than 50 minutes." The phrase "about 1.5" was clearly illustrated by the error bar in Figure 1. Examining of Figure 1 clearly reveals that the ratios of the second glucose concentration determined at 15 minutes, 30 minutes, and 45 minutes over the first glucose concentration all are larger than 1.5. The threshold value of 1.5 is taught in the paragraph bridging page 18 and page 19. As such, Applicants respectfully request withdrawal of this rejection in view of the foregoing reasons.

Rejections Under 35 USC 103

Claims 1-6 were rejected under 35 USC 103(a) as being unpatentable over March (US 6,681,127) in view of Brzheskii et al (Derwent SU 1534406) and the American Diabetes Association (2002). For the following reasons, the Examiner's rejection is respectfully traversed.

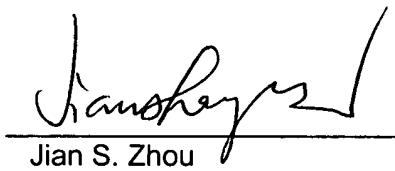
Applicants respectfully submit that a prima facie case of obviousness has **not** been established, because the primary reference (March), alone or in combination with the secondary references (Brzheskii et al., and ADA), does not disclose or suggest all of the limitations of the invention as currently claimed. The primary reference (March) does not disclose nor suggest anything about determining by means of the glucose-sensing ophthalmic device a second glucose concentration in the ocular fluid of a patient without fasting at a period of time of less than 50 minutes after orally administering of the load of carbohydrate; anything about comparing the second glucose concentration with the first glucose concentration to determine if the second glucose concentration is at least about 1.5 folds of the first glucose concentration, indicating that the patient is likely to be a diabetic. The first secondary reference (Brzheskii et al.) does not disclose nor suggest anything about determining by means of the glucose-sensing ophthalmic device a second glucose concentration in the ocular fluid of a patient without fasting at a period of time of less than 50 minutes after orally administering of the load of carbohydrate; anything about comparing the second glucose concentration with the first glucose concentration to determine if the second glucose concentration is at least about 1.5 folds of the first glucose concentration, indicating that the patient is likely to be a diabetic. The second secondary reference (ADA) cannot fill the gap left by the primary reference and by the first secondary reference. It is true that ADA disclose a threshold value, 126 mg/dL, of fasting plasma glucose for diabetes and a threshold value, 200 mg/dL, of plasma glucose after 2-hour glucose tolerance test for diabetes. But, these are threshold values for diagnosis purpose. One value is sufficient for diagnosis. There is no teachings and suggestions in ADA related to comparing of these threshold values, and related to comparing of one glucose concentration of a patient without fasting to another glucose concentration determined after the patient orally took a load of carbohydrate. Such comparison of two glucose concentrations determined before and after orally administering a load of carbohydrate to a patient without fasting has not been disclosed in any one of the cited references including ADA. As such, the primary reference, alone or in combination with the secondary reference, does not discloses nor suggest all of the limitations of the invention as currently claimed. Thus, a *prima facie* case of obviousness has not been established. Applicant respectfully requests withdrawal of the 35 U.S.C. §103(a) rejection.

CONCLUSION

In view of the foregoing and in conclusion, the Applicant submit that the rejections set-forth in the Office Action have been overcome, and that all pending claims are now in conditions for allowance.

Should the Examiner believe that a discussion with Applicants' representative would further the prosecution of this application, the Examiner is respectfully invited to contact the undersigned. The Commissioner is hereby authorized to charge any other fees which may be required under 37 C.F.R. §§1.16 and 1.17, or credit any overpayment, to Deposit Account No. 50-2965.

Respectfully submitted,



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